

HAND SANITIZER- alcohol gel
Laboratorio Salutec, S.A. de C.V.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

This is a gel hand sanitizer

The hand sanitizer is manufactured using only the following ingredients consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.
- e. Carbomer 940
- f. Trolamine

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Gel Hand Sanitizer

Use

Gel Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP, carbomer 940, trolamine

Package Label - Principal Display Panel

Drug Facts / Datos del Medicamento

Active Ingredient/ Ingredientes Activos
ETHYL ALCOHOL 70% / ALCOHOL ETILICO 70% v/v

Purpose/ Propósito
ANTISEPTIC / ANTISEPTICO

Uses: Hand sanitizer/ Usos: Sanitizante para manos

Alcohol-based solution that provides instant hand cleaning. Eliminates 99.9% of germs and bacteria leaving skin fresh, moisturized and hydrated. No need to rinse. / Solución base alcohol que brinda una limpieza instantánea para manos. Elimina el 99.9% de los gérmenes y bacterias dejando la piel fresca, humectada e hidratada. No necesita enjuague.

Warnings: For external use only. Flammable. Keep away from heat or flame.
Precauciones: Solo para uso externo. Inflamable. Mantener alejado del calor o las llamas.

Do not use / No utilizar
• in children less than 2 months of age / en niños menores de 2 meses
• on open skin wounds / en heridas abiertas de la piel

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water / Cuando use este producto, evite contacto con ojos, oídos y boca. En caso de contacto con los ojos, enjuague bien los ojos con agua.

Stop use and ask a doctor if irritation or rash occurs. There may be signs of a serious condition. / Suspense su uso y consulte a un médico si se produce irritación o sarpullido. Estos pueden ser signos de una afección grave.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away / Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.

Directions / Instrucciones
• Place enough product on hands to cover all surfaces. Rub hands together until dry / Coloque suficiente producto en las manos para cubrir todas las superficies. Frota las manos juntas hasta que se sequen.
• Supervise children under 6 years of age when using this product to avoid swallowing / supervise a los niños menores de 6 años cuando usen este producto para evitar que lo traguen.

Other information/ Otra información
• Store between 15-30°C (59-86 °F) / almacenar entre 15-30°C (59-86°F)
• Avoid freezing and excessive heat above 40C (104F) / Evite la congelación y el calor excesivo por encima de 40°C (104°F)

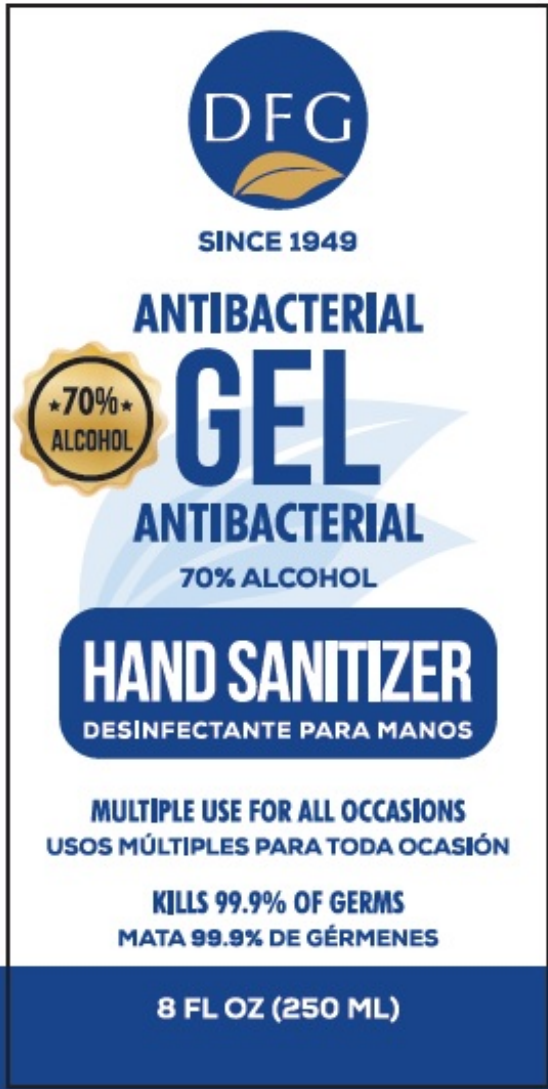
Inactive Ingredient: distilled water, hydrogen peroxide, glycerin, triethanolamine, Carbomer copolymer type A.
Ingredientes Inactivos: Agua destilada, Peróxido de hidrógeno, glicerina, trietanolamina, Copolímero de carbómero tipo A .

MADE IN MEXICO BY / HECHO EN MÉXICO POR:
Laboratorio Solutec S.A. de C.V.
Tel. 52(55) 5160 5969

LOTE/CAD:



7 506344 001855



250 mL NDC: 79289-

003-01

HAND SANITIZER			
alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79289-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	73 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 g in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	25.225 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.25 g in 100 mL
2,4,5-T-TROLAMINE (UNII: 9007L1DAXM)	0.4 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79289-003-01	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Laboratorio Salutec, S.A. de C.V. (951580007)**Establishment**

Name	Address	ID/FEI	Business Operations
Laboratorio Salutec, S.A. de C.V.		951580007	manufacture(79289-003)

Revised: 7/2020

Laboratorio Salutec, S.A. de C.V.